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(54) Stent with variable features to optimize support and method of making such stent

(57) An intravascular stent especially suited for implanting in curved arterial portions or ostial regions. The stent can include an end region which is fabricated to have a greater radial strength than the remaining axial length of the stent. Such a stent is particularly suited for use in ostial regions, which require greater support near the end of the stent. The stent alternatively can include sections adjacent the end of the stent with greater bending flexibility than the remaining axial length of the stent. Such a stent is particularly suited for use in curved arteries. The stent can also be constructed with an end that has greater radial strength and sections adjacent the end with greater bending flexibility. Such a stent prevents flaring of the stent end during insertion.

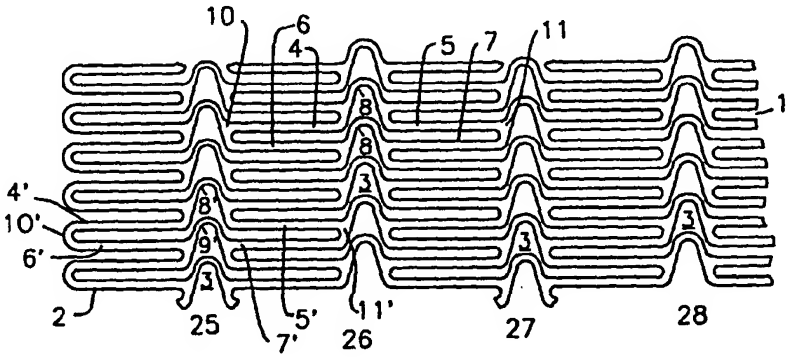

FIG. 1

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It is an object of this invention to provide a stent which does not have sharp points or protrusions at its end concentrating pressure on the vessel's wall upon expansion of the stent in a curved portion of a vessel.

It is another object of this invention to provide a stent having a radial force at its distal end that is greater than the radial force in the portion of the stent proximal to the distal end.

It is yet another object of this invention to provide an expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, wherein the cells disposed in the distal row of the stent are adapted to exert greater radial force and are further adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal end of the stent.

It is still another object of this invention to provide an expandable stent, comprising: a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of said stent and a proximal row disposed at the proximal end of the stent, wherein the cells in the distal row of the stent and the cells disposed in the proximal row of the stent are adapted to exert greater radial force and are further adapted to be more flexible than the cells disposed in the rows disposed between the distal row and the proximal row.

It is another object of this invention to provide an expandable stent, comprising: a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent.

It is yet another object of this invention to provide an expandable stent, comprising: a) a plurality of interconnected flexible cells defining a longitudinal stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row, and the row proximal to the distal row, are provided with first and second flexible connectors that are more flexible than the flexible connectors in the other rows of the stent.

It is a further aspect of this invention to provide an expandable stent comprising: a) a plurality of flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of flexible rows along the longitudinal axis with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member; b) a first C-shaped loop disposed between the first member and the third member; c) a second C-shaped loop disposed between the second member and the fourth member; d) a first flexible connector disposed between the first member and the second member; and e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the cells of the proximal row are provided with second and fourth members that are shorter than the first and third members in the proximal row, and wherein the distal row, and the row proximal to the distal row, and the proximal row and the row distal to the proximal row are provided with first and second flexible connectors that are more flexible than the flexible connectors in the other rows of the stent.

It is yet another object of this invention to provide an expandable stent, comprising: a plurality of flexible cells defining a stent having a proximal end and a distal end, the stent provided with means for imparting a radial force at its distal end that is greater than the radial force in the portion of the stent proximal to the distal end.

It is yet a further object of this invention to provide

is disposed between the second member 5 and the fourth member 7. In each of the cells 3, first member 4, second member 5, third member 6, and fourth member 7 are substantially equal. Thus, first C-shaped loop 10 is displaced a distance D1 and second C-shaped loop 11 is displaced a distance D2 from the center of cell 3. In a preferred embodiment, D1 is substantially equal to D2. A first flexible connector 8 is disposed between the first member 4 and the second member 5 and a second flexible connector 9 is disposed between third member 6 and fourth member 7. The flexible connectors 8 and 9 may be made in a variety of shapes, e.g., an "S" or a "Z" shape as shown in FIG. 11. In a preferred embodiment, a "U" shape is utilized as shown in Figs. 1 to 10.

Fig 1 shows the pattern or stent 1 in an unexpanded state, i.e., that state in which the stent 1 is first inserted in a particular vessel in which a balloon angioplasty procedure is to be performed, but before balloon inflation. Fig 2 shows the pattern of stent 1 in a partially expanded state, i.e., that state after the balloon has been expanded, e.g. by a balloon, and the state in which the stent 1 remains in the vessel which it supports. The plurality of interconnected cells 3 and 3' form a plurality of interconnected rows 25, 26, 27, and 28 of cells disposed along the longitudinal axis of the stent 1. Figs. 1 and 2 show a distal row 25 disposed at the distal end 2, a row 26 adjacent to and proximal to distal row 25, a row 27 adjacent to and proximal to row 26, and a row 28 adjacent to and proximal to row 27. It will be appreciated that the number of rows, and the number of cells per row, and the shape of each cell, may be varied as specific applications require.

As shown in Figs. 1 and 2, the cells 3' in distal row 25 differ from the cells 3 in rows 26, 27, and 28. The first member 4' and the third member 6' of the cells 3' in row 25 are shorter than the first member 4 and the third member 6 of the cells 3 in rows 26, 27 and 28. In cell 3', first member 4' is substantially equal to third member 6', however, first member 4' and third member 6' are shorter than second member 5' and fourth member 7'. The shorter members 4' and 6' result in a first C-shaped loop 10' that is not disposed as far away from the center of the cell 3' as second C-shaped loop 11'. Thus, first C-shaped loop 10' may be thought of as being "shorter" than second C-shaped loop 11'. As shown in FIG. 2, first C-shaped loop 10' is disposed a distance D1' that is less than the distance D2' that second C-shaped loop 11' is disposed from the center of the cell 3'. In an especially preferred embodiment, D1' is about 15% less than D2'.

Figs. 1 and 2 also show that the distal row 25 of the stent 1 is provided with a first U-shaped loop 8' and a second U-shaped loop 9' that are more flexible than the first U-shaped loop 8 and second U-shaped loop 9 of cells 3 in rows 26, 27, and 28 of the stent 1. This greater flexibility in the U-shaped loops 8' and 9' may be accomplished in a variety of ways, for example, by utilizing a different material, by treating the material e.g., by utilizing stainless steel annealing to impart selective degrees of hardness to the different portions of the stent. Alternatively, if, e.g., NiTi (Nitinol) is utilized, selected portions of the stent may be selectively thermomechanically treated so that portions of the stent, e.g., the U-shaped members, will remain in a martensitic phase while other portions of the stent will be transformed into austenitic phase in this section to yield different properties. Greater flexibility may also be achieved by changing the shape of the "U", for example to a "Z" or an "S" (as shown in FIG. 11), or by reducing the amount of material utilized to make the U-shaped loops 8' and 9'. In the embodiment shown in Figs. 1 and 2, the U-shaped loops 8' and 9' of row 25 are provided with the same thickness of material as the U-shaped loops 8 and 9 of the cells 3 in rows 26, 27, and 28, however, U-shaped loops 8' and 9' are not as wide. As shown in Figs. 1 and 2, U-shaped loops 8' and 9' have a width W1 that is less than the width W2 of U-shaped loops 8 and 9 in the cells 3 of rows 26, 27, and 28. In a preferred embodiment, W1 is about 50% narrower than W2. In an especially preferred embodiment, W1 is about 40% narrower than W2.

Fig. 3 is a side-by-side comparison of two stent sections and shows a conventional stent 12 compared to the stent 1, shown in Figs. 1 and 2. Fig. 4 shows stents 1 and 12 shown in Fig. 3 as they appear when they are crimped on a balloon and bent as they would be during insertion around a curve in a vessel. As shown in Fig. 4, conventional stent 12 flares at its leading edge 13 in contrast to stent 1 which does not. Fig. 5 shows the stents of Fig. 4 after the stents have been expanded in a curve. The tip of conventional stent 12 produces a protrusion or sharp point 13 which could cause local pressure and possible trauma to the vessel wall. In contrast, the stent 1 constructed in accordance with the invention bends gently at its end 2 without forming a protrusion or sharp point because the deformation of the of U-shaped loops 8' and 9' in distal row 25 make the end 2 softer.

Fig. 6 shows the stents 1 and 12 of Fig. 3 at partial expansion (before reaching maximum pressure) disposed on a substantially straight catheter. As shown, although the two stents 1 and 12 are subjected to the same outward force, the end 2 of stent 1 is less expanded than the end 13 of conventional stent 12 demonstrating the increased radial force of the end 2 of stent 1 constructed in accordance with the invention. At full pressure the radii of the stents 1 and 12 will be equal, however, the end 2 of stent 1 will have greater radial resistance to collapse than the end 13 of stent 12.

Fig. 7 shows an alternative embodiment of the invention. As shown in Fig. 7, the cells 3' in row 25 are provided with a first member 4' and third member 6' that are shorter than second member 5' and fourth member 7'. The cells 3' in row 25 are provided with a first U-shaped loop 8' and a second U-shaped loop 9' that are thinner than the U-shaped loops 8 and 9 in the cells 3 in rows 27 and 28. The cells 3" in row 26 are provided with

than the gauge of the material utilized in the cells disposed between the distal row and the proximal row of the stent.

8. The stent of claim 5, wherein the cells in the distal row and the proximal row are made of a material that is more flexible than the material utilized in the cells disposed between the distal row and the proximal row of the stent.

9. An expandable stent, comprising:

a) a plurality of interconnected flexible cells defining a stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member and, a fourth member;
b) a first C-shaped loop disposed between the first member and the third member;
c) a second C-shaped loop disposed between the second member and the fourth member;
d) a first flexible connector disposed between the first member and the second member; and
e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row is provided with first and second flexible connectors that are more flexible than the flexible connectors in the cells in the other rows of the stent.

10. The stent of claim 9, wherein the first and the second flexible connectors are U-shaped.

11. The stent of claim 9, wherein the first and the second flexible connectors are S-shaped.

12. The stent of claim 9, wherein the first and the second flexible connectors are Z-shaped.

13. The stent of claim 9, wherein the first and the third members in the distal row are about 15% shorter than the second and the fourth members in the distal row.

14. The stent of claim 9, wherein the first and the second flexible connectors in the distal row are narrower than the first and the second flexible connectors in the cells in the other rows of the stent.

15. The stent of claim 14, wherein the first and the second flexible connectors in the distal row are about 40% narrower than the first and the second flexible connectors in the cells in the other rows of the stent.

16. The stent of claim 9, wherein the first and the second flexible connectors in the distal row are annealed to impart a hardness that is different than the hardness of the flexible connectors in the other rows of the stent.

17. The stent of claim 9, wherein the stent is comprised of NiTi and the first and the second flexible connectors in the distal row of the stent are in a martensitic phase and the remaining portions of the stent are in the austenitic phase.

18. The stent of claim 9, wherein the cells in the distal row are of a thinner gauge than the gauge of the material utilized in the cells disposed between the distal row and the proximal end of the stent.

19. The stent of claim 9, wherein the cells in the distal row are made of a material that is more flexible than the material utilized in the cells disposed between the distal row and the proximal end of the stent.

20. An expandable stent, comprising:

a) a plurality of interconnected flexible cells defining a longitudinal stent having a proximal end and a distal end and a longitudinal axis, the cells arranged in a plurality of interconnected flexible rows disposed along the longitudinal axis of the stent with a distal row disposed at the distal end of the stent and a proximal row disposed at the proximal end of the stent, each of the flexible cells comprising a first member, a second member, a third member, and a fourth member;
b) a first C-shaped loop disposed between the first member and the third member;
c) a second C-shaped loop disposed between the second member and the fourth member;
d) a first flexible connector disposed between the first member and the second member; and
e) a second flexible connector disposed between the third member and the fourth member, wherein the cells of the distal row are provided with first and third members that are shorter than the second and fourth members in the distal row, and wherein the distal row, and in the row proximal to the distal row, are provided with first and second flexible connectors that are more flexible than the flexible connectors in the other rows of the stent.

21. The stent of claim 20, wherein the first and the sec-

tors in the distal row, the row proximal to the distal row, the proximal row, and the row distal to the proximal row are annealed to impart a hardness that is different from the hardness of the first and the second flexible connectors in the cells disposed in the other rows of the stent.

39. The stent of claim 31, wherein the stent is comprised of NiTi and the first and the second flexible connectors in the distal row, the row proximal to the distal row, the proximal row, and the row distal to the proximal row are in a martensitic phase and the remaining portions of the stent are in the austenitic phase.

40. The stent of claim 31, wherein the cells in the distal row, the row proximal to the distal row, the proximal row, and the row distal to the proximal row are of a thinner gauge than the gauge of the material utilized in the cells disposed in the other rows of the stent.

41. The stent of claim 31, wherein the cells in the distal row, the row proximal to the distal row, the proximal row, and the row distal to the proximal row of the stent are made of a material that is more flexible than the material utilized in the cells disposed in the other rows of the stent.

42. An expandable stent, comprising: a plurality of flexible cells defining a stent having a proximal end and a distal end, the stent provided with means for imparting a radial force at the distal end that is greater than the radial force in the portion of the stent proximal to the distal end.

43. The stent of claim 42 further provided with means for imparting flexibility to the distal end of the stent that is greater than the flexibility of that portion of the stent proximal to the distal end.

44. An expandable stent, comprising: a plurality of flexible cells defining a stent having a proximal end and a distal end, the stent provided with means for imparting a radial force at its proximal and distal ends that is greater than the radial force of that portion of the stent disposed between the proximal and distal ends.

45. The stent of claim 44 further provided with means for imparting flexibility to the distal end of the stent and the proximal end of the stent that is greater than the flexibility of that portion of the stent disposed between the proximal and distal ends.

46. An expandable stent for treating a lumen having a unique characteristic along a portion of the lumen, comprising: a plurality of interconnected flexible cells, the cells arranged in a plurality of interconnected flexible rows defining a stent having a proximal end and a distal end and a longitudinal axis, wherein at least one of the rows is adapted to accommodate the unique characteristic of that portion of the lumen in contact with the adapted row.

47. An expandable stent for treating a lumen having a non-uniform diameter, comprising: a plurality of interconnected flexible cells, the cells arranged in a plurality of interconnected flexible rows defining a stent having a proximal end and a distal end and a longitudinal axis, wherein at least one of the rows is adapted to accommodate the non-uniform diameter of the portion of the lumen in contact with the adapted row.

48. An expandable stent for treating a lumen having a non-uniform radial force, comprising: a plurality of interconnected flexible cells, the cells arranged in a plurality of interconnected flexible rows defining a stent having a proximal end and a distal end and a longitudinal axis, wherein at least one of the rows is adapted to accommodate the non-uniform radial force of the portion of the lumen in contact with the adapted row.

49. An expandable stent for treating a lumen having a non-uniform longitudinal flexibility, comprising: a plurality of interconnected flexible cells, the cells arranged in a plurality of interconnected flexible rows defining a stent having a proximal end and a distal end and a longitudinal axis, wherein at least one of the rows is adapted to accommodate the non-uniform longitudinal flexibility of the portion of the lumen in contact with the adapted row.

50. The stent of claim 46, wherein one of the plurality of rows disposed between the proximal end and the distal end is provided with a cell size that is larger than the cells in the remaining rows.

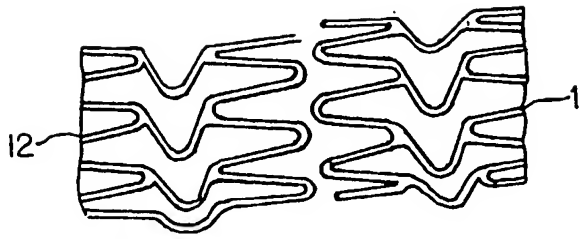

FIG. 3

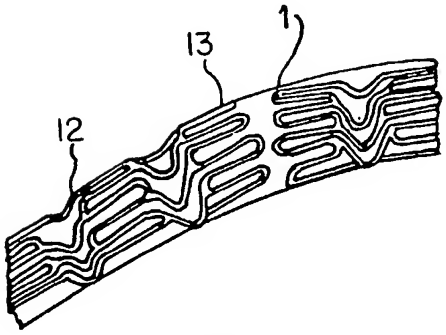

FIG. 4

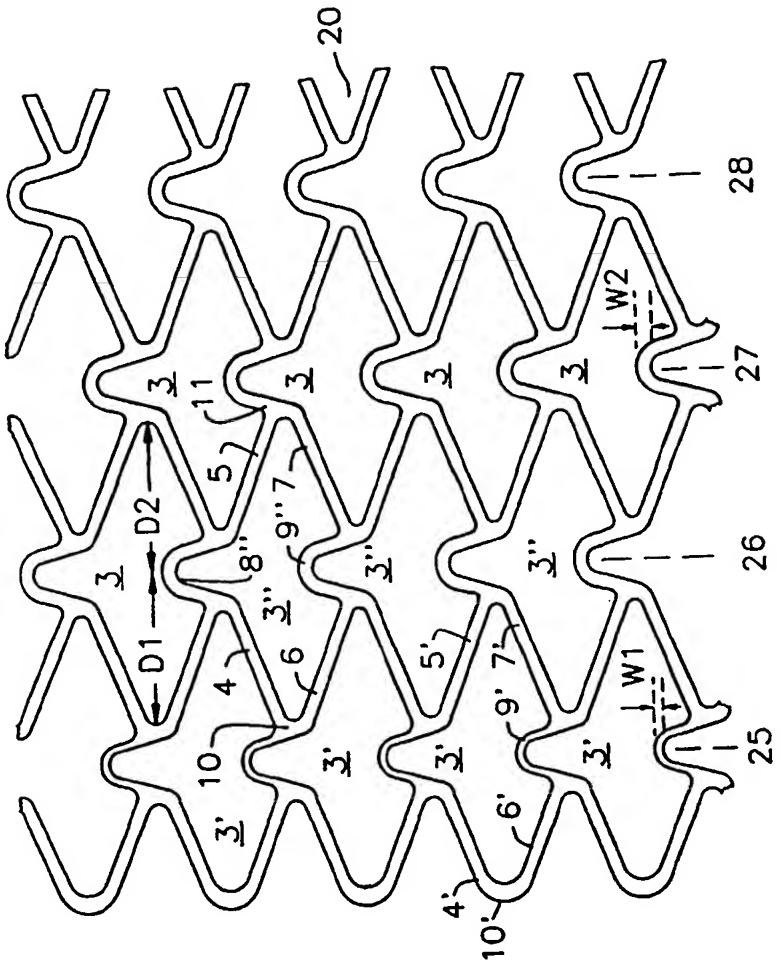

FIG. 7

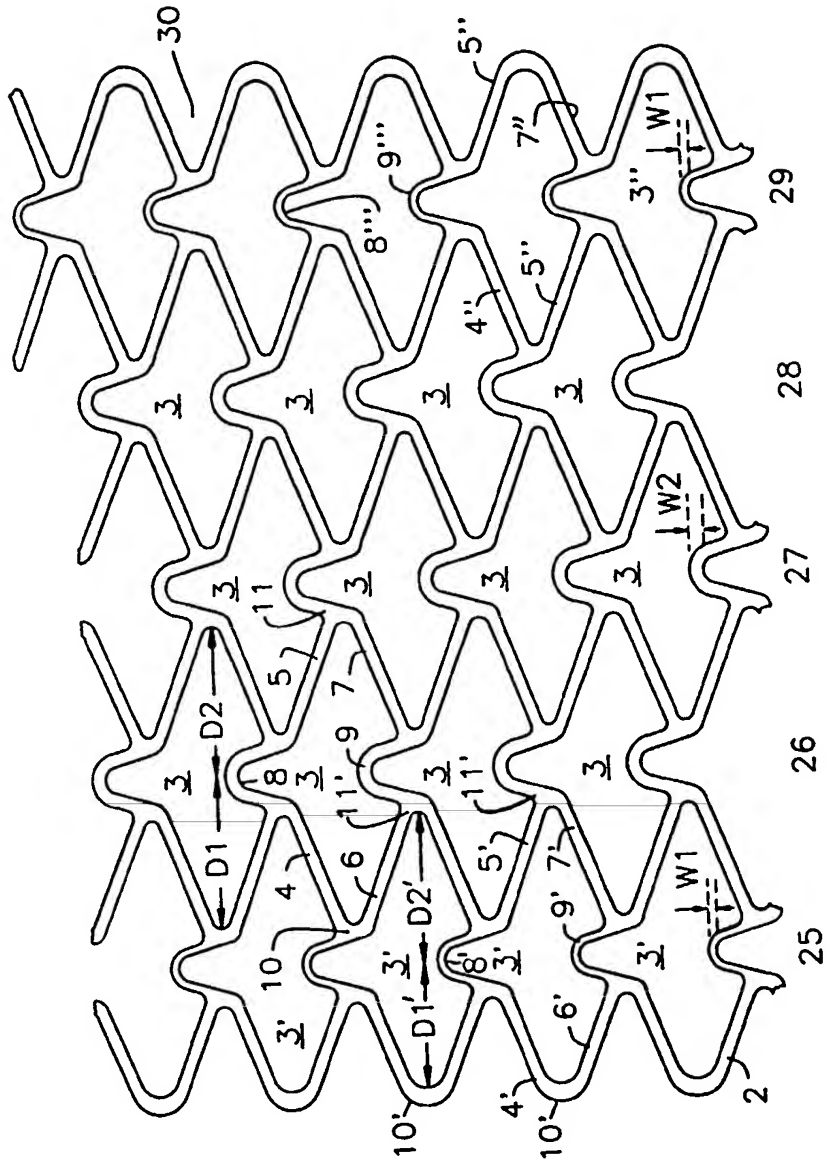

FIG. 10

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 11 3109

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X A	WO 96 26689 A (SCIMED LIFE SYSTEMS) * page 5, line 4 - line 8; figure 4 *	46-50 2,6	A61F2/06
X	EP 0 541 443 A (MEADOX FRANCE) * the whole document *	42,44, 46-50	
A	WO 95 31945 A (SCIMED LIFE SYSTEMS) * abstract; figures *	17,28	
E	EP 0 800 801 A (ADVANCED CARDIOVASCULAR SYSTEMS) * the whole document *	1-8	
E	WO 97 40781 A (JANG) * page 16, line 5 - page 17, line 25; figures 6A,,6B,7B *	1,3,5,7	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	17 December 1997	Hagberg, A

CATEGORY OF CITED DOCUMENTS

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